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Croatia

Agricultural Biotechnology Annual

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Report Highlights:
Croatia is a net food importer and the government policy is geared towards raising agricultural productivity and, to a lesser extent, controlling imports. Although Croatia has adopted the European Union's biotech legislation, Croatia remains part of a group of EU member states that maintain more stringent national biotech policies than the EU norm. Croatia believes its competitive advantage in agricultural products will be realized by seeking a premium for high quality "natural" products rather than competing on volume. Thus, there is a concern about the potential market consequences of adopting pro-biotech policies as well as a strong bias against genetically engineered products as somehow being "unnatural". Additionally, Croatian politicians and the general public remain misinformed about biotech products and view them as potentially dangerous.

Section I. Executive Summary:

Croatia is a net food importer. While the current goal of Croatia's agricultural policy is to increase productivity, the focus is on greater market recognition of Croatia's geographic indications and linking agricultural production to tourism.

Although Croatia has adopted the European Union's biotech legislation, Croatia remains part of a group of EU member states that maintain more stringent national biotech policies than the EU norm. Croatia believes its competitive advantage in agricultural products will be realized by seeking a premium for high quality "natural" products rather than competing on volume. Thus, there is a concern about the potential market consequences of adopting pro-biotech policies as well as a strong bias against genetically engineered products as somehow being "unnatural". Additionally, Croatian politicians and the general public remain misinformed about biotech products and view them as potentially dangerous. In 2004 and 2005, the government randomly tested foods and seeds specifically for biotech content. Several products had to be withdrawn from the market due to a lack of proper biotech labeling. Croatia now regularly tests products for biotech events at the border and in the market. The testing is performed in accordance with Croatia's annual inspection plans for Sanitary Inspection, which is determined based on available fiscal resources

Several pieces of legislation regulate the importation and cultivation of biotech crops and foods. The laws regulating biotechnology include the Law on Genetically Modified Organisms (GMOs), the Law on the Application of the EU Regulation 258/97 on Novel Food and Novel Food Ingredients, the Law on the Application of the EU Regulation 1829/2003 on GMO Food and Feed and Regulation 1830/2003 on Traceability and Labeling of Food and Feed Derived from GMOs that Amends EU Directive 2001/18/EC, the Law on the Application of EU Regulation 1946/2003 on Trans-boundary Movement of GMOs and the Food Act.

Croatia's law on GMOs bans the release of genetically engineered (GE) plants in protected areas and their buffer zones, in areas of organic farming, and in areas that are of importance to ecotourism. The law provides a legal tool for excluding most of the country from planting GE plants. Moreover, all 21 Croatian counties have declared themselves to be GMO free. To date, no permits have been granted for the deliberate release of GE plants -- either for field trials or commercial cultivation in Croatia nor have there been any applications to Croatian authorities for food or feed use. However, all EU approved events are, in theory, automatically approved for use in Croatia. Nevertheless, if given an option, Croatia could be expected to decide on an opt-out on all EU level approved biotech products. Currently, all these products must be labeled and when it comes to food and feed, for traceability purposes, the company must inform the Ministry of Health 30 days in advance before placing on the Croatian market.

For more information on the EU-27(28) biotech situation please refer to EU-27 Agricultural Biotech Report.

Section II. Author Defined:

Chapter 1: Plant Biotechnology

Part A: Production and Trade

a. Product Development: Croatia is not developing any biotech crops.

b. Commercial Production: In theory, all EU approved events are automatically approved for use in Croatia after one year of variety testing. However, Croatia's law on Genetically Modified Organisms (GMOs) bans the release of GMOs in protected areas and their buffer zones, in areas of organic farming, and in areas that are of importance to ecotourism. The law provides a legal tool for excluding most of the country from planting GMOs. Moreover, all 21 Croatian counties have declared themselves to be GMO free. To date, in Croatia, no permits have been granted for the deliberate release of GE plants -- either for field trials or commercial cultivation.

c. Export: Croatia does not export GE crops/products.

d. Import: To date, in Croatia, no permits have been granted for the deliberate release of GE plants -- either for field trials or commercial cultivation -- nor have any applications been made to approve genetically engineered food or feed products. However, all EU approved events are automatically approved for use in Croatia. These products must be labeled and when it comes to food and feed, for traceability purposes, the company must inform the Ministry of Health 30 days in advance before they are placed on the Croatian market. Some imported GM soy beans are used in feed and the press has reported that some farmers are planting imported GM soy.

d. Food AID Recipient Countries: Croatia is not a food aid recipient.

Part B: Policy

a. Regulatory framework:

The following laws together regulate the importation, transshipment, production, usage, and sale of products of agricultural biotechnology (all food, feed, and seed): The Law on GMOs (Governmental Gazette 70/2005, 137/2009, 28/2013, 47/2014), the Law on the Application of the EU Regulation 258/97 on Novel Food and Novel Food Ingredients (Governmental Gazette 18/2013, Governmental Gazette 47/2014), the Law on the Application of EU Regulation 1829/2003 on GMO Food and Feed and Regulation 1830/2003 on Traceability and Labeling of Food and Feed Derived from GMOs that Amends EU Directive 2001/18/EC (Governmental Gazette 18/2013), the Law on the Application of EU Regulation 1946/2003 on Trans-boundary Movement of GMOs (Governmental Gazette 81/2013) and the Food Act (Governmental Gazette 81/2013).

The Law on GMOs incorporates the following EU regulations and directives: Directive 2001/18/EC, Directive 2009/41/EC, Regulation 1829/2003, Regulation 641/2004, Regulation 1981/2006, Regulation 1830/2003 and Regulation 65/2004.

The Law on the Application of the EU Regulation 258/97 on Novel Food and Novel Food Ingredients deals with all aspects of the novel food, that is, with all foods which were not consumed in the EU to a significant degree before May 1997.

The Law on Application of the EU Regulation 1829/2003 on GMO Food and Feed and Regulation 1830/2003 on Traceability and Labeling of Food and Feed Derived from GMOs that Amends EU Directive 2001/18/EC and the Law on Application of the EU Regulation 1946/2003 on Trans-boundary Movement of GMOs came into effect with Croatian EU accession. These two laws establish the responsible bodies and their tasks relating to the handling of biotechnology products as well as the penalties for breaching the provisions of these laws.

The Food Act governs the responsible bodies and their tasks, responsibilities of stakeholders in food and feed handling, official controls and legal measures for the application of the following EU legal documents: Regulation 178/2002, Regulation 1304/2003, Regulation 2230/2004, Regulation 178/2002, Regulation 608/2004, Regulation 115/2010, Regulation 16/2011, Regulation 931/2011, Regulation 178/2002, Regulation 208/2013, Decision 2004/478/EC, Regulation 1760/2000 and all other EU legal acts enacted for application of the before mentioned legislation.

i. Responsible Ministries and Their Roles:

The Ministry of Science (MOS), Education and Sport: According to the Law on GMOs, the MOS is responsible for the limited and contained use of genetically engineered products. If an institute wanted to do research on genetically engineered products, it would have to apply to the MOS.

The Ministry of Health (MOH): According to the Food Act, the MOH is responsible for all issues relating to food, foodstuff, and feed containing biotechnology content and inspections. Additionally, the Law on GMOs proscribes that MOH oversee the usage and inspection of GMO products in cosmetics, pharmaceutical products, and products for human health protection. According to the Law on GMOs, the MOH is the umbrella ministry and coordinating body for all biotechnology issues. Furthermore, the Law on the Application of EU Regulation 1829/2003 on GMO Food and Feed and Regulation 1830/2003 on Traceability and Labeling of Food and Feed Derived from GMOs that Amends EU Directive 2001/18/EC names the Ministry of Health as the lead Ministry for implementation of the mentioned EU Regulations although sometimes the Ministry of Agriculture has to be consulted.

The Service for Biodiversity in the Ministry of Environment Protection and Nature (MEPN): According to the Law on GMOs the Ministry of Culture is responsible for the intentional introduction of GMOs into the environment. In 2012, MEPN replaced the Environment Protection Directorate in the Ministry of Culture (MOC): Furthermore, according to the Law on the Application of EU Regulation 1946/2003 on Trans-boundary Movement of GMOs, MEPN is responsible for implementing the regulation and coordinating its activities with the Ministry of Health, the Ministry of Agriculture and Croatian Customs.

The Ministry of Agriculture (MOA): According to the Food Act, the Ministry of Agriculture is responsible for coordinating official inspections and is the EU's contact point. According to the

Law on GMOs, the MOA has responsibility for inspections of biotech feed; biotech reproduction material in agriculture and veterinary medicine; and drugs in veterinary medicine and pesticides. Furthermore, the MOA is responsible for giving its consent for the intentional release of biotech products into the environment.

ii. Role and Membership of Biosafety Committee (if any):

The Law on GMOs required the establishment of a Council for GMOs with the specific task of assisting governmental bodies to apply the Law. The Council has 17 members appointed by the Government of Croatia based on nominations from the pertinent Ministries. Council membership lasts for four years. The Council's work is independent and public. According to the Law, the Council's tasks include: tracking gene technology development and usage, tracking scientific breakthroughs and giving opinion and incentives for usage of gene technology and GMOs, giving opinions on social, ethical, technical, scientific, and other conditions of GMO use, advising responsible institutions on GMO and gene technology issues, informing the public on GMO and gene technology development, and presenting viewpoints and opinions.

The Law on GMOs also calls for establishing a Board for Limited Usage of GMOs with 11 members composed of scientists from the fields of microbiology, genetics, medicine, biochemistry, molecular biology, pharmacy, biotechnology, agriculture, forestry, veterinary medicine, nature and environmental protection, and occupational protection. In addition, the Law on GMOs requires the establishment of a board for the introduction of biotech products into the environment that consists of nine scientists from the fields of: genetics, ecology, nature protection, environmental protection, agriculture, forestry, veterinary medicine, biochemistry, molecular biology, microbiology, and medicine. The tasks of these boards include: giving opinions on biotech usage in terms of legal procedures as outlined by the Law on GMOs; giving opinions and proposals for preparing other legislation on GMO usage; and giving opinions and proposals to responsible ministries on biotech usage issues and other expert work as outlined by the GMO Law and related regulations. According to the law, these two boards should report to the GMO Council once a year. The Board for Limited Usage of GMOs last met on April 11, 2012, when it reviewed some laboratory research requests. The Board for the Introduction of Biotech Products into the Environment last met on January 28, 2011, when it discussed as part of Croatia's compliance with the EU's biotech policies amending the regulation relating to the threshold below which products do not have to be labeled as containing GMOs. Most of the debate related to the use and marketing of GMO plants containing a gene nptII. The Board concluded that there is no reason to delay placing on the market products that contain up to 0.9% of the nptII selectable marker. However, in the case where the intent is to market a GM plant that contains the nptII selectable marker, the Board determined that it needs to deliver a separate opinion.

Both the old and new Food Act call for the establishment of a Croatian Food Agency (CFA). The CFA began its work in 2004 and provides scientific and technical support to legislators as well as scientific advice in all areas that directly or indirectly influence food and feed safety. Additionally, the Food Agency provides scientific opinions to the Ministry of Health and the Ministry of Agriculture regarding the placement of GMO food and/or feed on the market. As a cost savings measure, it is expected that CFA will soon be merged together with the Croatian Veterinary Institute into one institution. This has inspired some debate by food safety experts who are concerned about

the continued independence of the CFA, as it is an important pillar of food safety in Croatia.

iii. Assessment of political factors that may influence regulatory decisions related to agricultural biotechnology:

Biotech opponents in Croatia have been emboldened by the perceived success of Austria and Slovenia in declaring themselves to be GMO free and have long advocated that Croatia position itself within this regional group of "healthy," GMO-free countries.

Currently, Croatia clearly sees its future as a niche market for "healthy foods" (NOTE: In Croatia, the word "healthy" encompasses everything from conventional and organic to non-biotech products). There has been limited demand for biotech seed imports to combat drought, pests, or soil problems. Government officials acknowledge the legal obligation to open their agricultural market to foreign imports, but actively declare Croatia to be GMO-free, as part of a strategy to promote the country as a "healthy" tourist destination. The Croatian public generally is opposed to biotech products. Therefore, if given an option, Croatia could be expected to decide on an opt-out on both the cultivation and use of all EU level approved biotech products although this could affect the cost of inputs for the livestock sector.

iv. Distinctions regarding the regulatory approval process for food, feed, processing, and environmental release are as follows:

There are similar long and complicated procedures to approve conventional and biotech food and feed products, but the approval process for environmental release is different. At the end of the regulatory procedure for food and feed, biotech products must gain special permission to market the product. Some agricultural seed varieties (biotech and conventional), however, must first go through a variety registration process. After the Croatian Seed and Seedlings Institute registers the variety, it is placed on the list of seed varieties that can be marketed in Croatia. Biotech seeds, in additional to variety registration, require special permission to be placed on the market, including permission for the intentional environmental release of GMOs.

b. Approvals: There have been no direct applications to Croatian authorities to approve biotech crops for food or feed use, but products with EU approved events can be sold in Croatia. If the biotech content is above 0.9%, the product must be labeled. The biotech threshold level drops to 0.0% for seed and biotech products that are not EU approved. The same applies to feed. In theory for genetically engineered seeds, Croatia will accept all EU approvals after a year of variety testing. However, Croatia has not approved any biotech seed varieties for planting nor are any biotech seed varieties in the process of being approved.

c. Field Testing: According to the Law on GMOs and subsequent Regulations, field tests of biotech crops are allowed after all the conditions prescribed by the Law and Regulations are satisfied. However, no such tests are currently being conducted in Croatia.

d. Stacked Events Approvals: Stacked events are treated the same as in the EU. Croatia hasn't issued its own specific guidelines.

e. Additional Requirements: Biotech food and feed products require special permission as GE products to be placed on the market. When placing on the Croatian market a GE food or feed that has been approved in the EU, the company must notify the Ministry of Health 30 days in advance for traceability purposes. Additionally, some agricultural seed varieties (regular and biotech) must go through a variety registration process before they are placed on the list of seeds that can be marketed in Croatia. Biotech seeds, in addition to variety registration, require special permission to be placed on the market, including permission for the intentional environmental release of GE plants. Croatia accepts all EU approved varieties after a year of variety testing.

f. Coexistence: The Law on GMOs forbids the planting of registered biotech crops in nature-protected areas, ecological areas, areas for organic agricultural production or eco-tourism, protected areas (i.e. as defined as impact zones within previously registered zones), and in areas defined as GMO-free zones by local government. In addition, biotech crop plantings for reproduction are allowed only in the areas that are designated by the Ministry of Agriculture and the Ministry of Environment Protection and Nature and approved by the Croatian Government in a special ordinance.

g. Labelling: According to the Law on the Application of EU Regulation 1829/2003 on GMO Food and Feed and Regulation 1830/2003 on Traceability and Labeling of Food and Feed Derived from GMOs that Amends EU Directive 2001/18/EC, food and feed containing agricultural biotechnology ingredients must have special, additional information on the label that informs consumers of all of its characteristics.

h. Trade Barriers: Beyond the current legislation, there are no additional pending, plant-biotechnology requirements with the potential to affect U.S. exports. A potential future exception could be legislation regarding bioengineered animals or actions relating to the "opt-out" amendments currently being discussed at the EU level.

i. Intellectual Property Rights: Biotech crops are not planted commercially in Croatia. Croatia has intellectual property rights legislation in place and is a member of The International Union for the Protection of New Varieties of Plants (UPOV).

j. Cartagena Protocol Ratification: Croatia signed and ratified the Cartagena Biosafety Protocol. Officially, there is no trade in biotech products, especially not in seeds. However, it is currently difficult to tell whether the Biosafety Protocol is being applied and working in practice. In addition, Croatia plans to ratify the following protocols: Nagoya-Kuala Lumpur Protocol and Nagoya Protocol.

k. International Treaties/Fora: Croatia is a member of the International Plant Protection Convention (IPPC), Codex Alimentarius (Codex), and the World Organization for Animal Health (OIE), but Croatia does not appear to take an active position regarding plant or animal biotechnology in these organizations.

l. Related Issues: Croatia regularly tests products for biotech events at the border and in the market. The testing is performed in accordance with Croatia's annual inspection plans for Sanitary

Inspection, which is determined based on available fiscal resources.

Croatia was in favor of the EU Commission opt-out proposal. It can be expected that the Croatian government, will use the opt-out provisions to restrict the planting, import and sale of GM crops and foods. In addition, Croatia is a signatory of the Danube Soya Agreement; a new initiative to increase non-GMO soy production in Europe and reduce GMO imports. The Danube Soya aims to create a GMO-free soy producing region in countries along the Danube River. Another goal of the project is to connect poorer farmers in Eastern European countries, such as Slovakia, Hungary, Croatia, and Serbia, to more affluent consumers in Western Europe who want non-GMO soy for feed or food. Current soybean production in Croatia is modest (roughly 120,000 tons from approximately 50,000ha). Nevertheless, more than one third of the production goes to export to neighboring countries, while at the same time Croatia imports between $80 and $100 million (mostly from Brazil, Slovenia, India, Italy, Russia, Argentina) in soy cake for feed.

m. Low Level Presence Policy: Croatia does not have a policy on low level presence.

Part C: Marketing

a. Market Acceptance: The average Croatian consumer views food derived from biotech crops negatively. Consequently, many farmers are afraid to grow biotech crops. There is a feeling that biotechnology is something unnatural and food should be natural. These negative opinions are based largely on emotions, not on an informed study of the issue.

c. Public/Private Opinions: Croatia has NGOs such as Green Peace and Green Action that are actively campaigning against biotechnology and the Croatian press has generally taken a negative stance on biotech.

c. Marketing Studies: A Croatian market research agency carried out a study in 2009 on "consumer recognition of healthy foods" that among other things researched the opinions and knowledge of Croatian consumers on GMOs. In this study, 51% of respondents said that they would not eat GMO food products under any circumstances and 29% of respondents thought that they did not know enough about GM foodstuffs. The study showed that 90% of respondents thought that GM foodstuffs should be clearly labeled on the store shelves.

The same agency did a study in 2005and 2008 on public opinion on GMOs. In this study, 67% (2005) and 58% (2008) of respondents said that they would not eat GM food products under any circumstances and only 16% (2005) and 26% (2008) of respondents thought that they didn't know enough about GM foodstuffs.

Part D: Capacity Building and Outreach

a. Activities: Below please find a list of the U.S. Government / USDA funded capacity-building/outreach activities that have been carried out in Croatia over the last two years:

2014: An expert was provided for the largest regional feed conference (KRMIVA): The topic of the

conference was Animal Feed. Mr. David Green, Senior Technical Consultant, U.S. Soybean Export Council spoke about: "The future of US soybean trade and the effects of anti-biotech policies".

2013: An expert was provided for the largest regional feed conference (KRMIVA): The topic of the conference was Animal Feed. Mrs. Gloria Gabellini, COCERAL spoke about "Providing for a safe, sustainable feed and food supply with modern technology and practices in grain and oilseeds production and use".

2012: Dr. Ralph Scorza, USDA/ARS plant breeding scientist described his research on a GE plum that is resistant to plum pox and Victor Felix Nicolescu, member of Romania's National Sanitary, Veterinary and Food Safety Authority discussed the US and EU regulatory frameworks for field trials.

2012: An expert was provided for the largest regional feed conference (KRMIVA): The topic of the conference was Animal Feed. Marco Pasti, Associazione Italiana Maiscoltori spoke about "Bt Corn in Italy: a missed opportunity for farmers and feeders".

b. Strategies and Needs: Discussion about the current situation with price and availability of GM feed versus non GM feed should be continued, given the lack of knowledge about the economic consequences of asynchronous approvals. Also, since Croatian politicians and the general public are not well informed about the safety of approved biotech products, efforts should continue to program credited scientific and food safety experts to raise general awareness.

Chapter 2: Animal Biotechnology

Part E: Production and Trade

a. Biotechnology Product Development: Genetic engineering and cloning are not being developed in Croatia for the production of agricultural animals.

b. Commercial Production: The Croatian livestock sector is not actively employing the use of genetically engineered animals or products derived from genetically engineered animals or clones.

c. Biotechnology Export/Imports: Croatia is neither exporting nor importing GE animals, livestock clones, or products from these animals. Bovine semen valued at $136,705 was imported from the United States in 2014, but it is unknown whether the genetic material was produced with modern biotechnology techniques.

Part F: Policy

a. Regulation: Beyond EU legislation, Croatia does not have in place any legislation specifically related to the development, commercial use and/or import of these animals or products. At present, food from clones falls under the scope of the Regulation on Novel Foods and Novel Food Ingredients (EC) 258/97 and is thus subject to pre-market approval based on a safety risk assessment.

b. Labeling and Traceability: There are indications that the Croatian Government may consider traceability and mandatory labeling requirements for products derived from GE and cloned animals. The government entities that would likely regulate these technologies for food and environmental safety issues relating to research on or commercial use of these animals include: the Ministry of Agriculture; the Ministry of Health; the Ministry of Environment Protection and Nature; the Ministry of Science, Education and Sport; the Croatian Food Agency, and the Council for GMOs.

c. Strict biotech legislation acts as a barrier to trade when it comes to biotechnology.

d. Intellectual Property Rights (IPR): Croatia has legislation on intellectual property rights, but does not have IPR legislation on animal biotechnology nor is that kind of legislation currently being considered.

e. International Treaties/Fora: Croatia is a member of the International Plant Protection Convention (IPPC), Codex Alimentarius (Codex), and the World Organization for Animal Health (OIE), but Croatia does not appear to take an active position regarding animal biotechnology in these organizations.

Part G: Marketing

a. Market Acceptance: The initial reaction to these products is unlikely to be favorable.

b. Public Private Opinions: There are active organizations that lobby against the genetic engineering or cloning of agricultural animals and Croatia's press historically hasn't been favorable to these types of innovations.

c. Marketing Studies: At this time, there are no known cloning or GE animal production market studies.

Part H: Capacity Building and Outreach

a. Activities: Croatia remains opposed to bioengineering in plants and efforts to promote animal biotechnology are even more sensitive.

b. Strategies and Needs: Raising questions about accessibility of quality animal genetics derived with techniques of modern biotechnology would be a good starting point for opening a discussion on this topic.